K011003

Diasol Inc.

APR 2 0 2001

II. 510K SUMMARY IN ACCORDANCE WITH SMDA '90

SUBMITTER:	DIASOL INC. 13212 RAYMER ST. NORTH HOLLYWOOD, CA 91605 PHONE (818) 255-1800 FAX (818) 982-8539
CONTACT	MONICA ABELES
DATE SUMMARY WAS PREPARED	March 29, 2001
NAME OF DEVICE	SAFESTING AND SAFESTING HUB
COMMON NAME	BUTTERFLY, WINGED INFUSION SET
CLASSIFICATION NAME	SET, ADMINISTRATION, INTRAVASCULAR 880.5440 CLASS II
PERFORMANCE STANDARD	NONE ESTABLISHED UNDER 514 OF FDA
PREDICATE DEVICE	DAISY PROTECTED SCALP VEIN SET BD VACUTAINER BRAND SAFETY-LOK NEEDLE HOLDER

DEVICE DESCRIPTION:

SAFESTING IS A STERILE, SINGLE USE DEVICE FOR BLOOD COLLECTION. IT CONSISTS OF A BUTTERFLY NEEDLE, SOFT TUBING AND A PROTECTIVE SHIELD (THAT WHEN ACTIVATED ENCLOSES THE NEEDLE PERMANENTLY TO PROVIDE PROTECTION FROM ACCIDENTAL NEEDLESTICKS), A TUBE HOLDER AND A PLASTIC MULTISAMPLE ADAPTOR FOR ACCESS INTO THE TUBE.
SAFESTING'S INNOVATIVE FEATURES ALLOW VERY EASY TUBE REMOVAL, AND CONTROL OVER BLOOD COLLECTION TUBE FILLING.
IT IS A ONE HANDED OPERATION WITH REGARDS TO CHANGING THE BLOOD COLLECTION TUBES. THE SAFETY FEATURE FOR THE BUTTERFLY IS COVERED UNDER DAISY'S 510K.
SAFESTING COMES IN A VERY WIDE RANGE OF SIZES 19 G-27 G THOUGH ALLOWING FOR APPROPRIATE SIZING FOR EACH USE.

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SAFESTING HUB CONSISTS OF THE PART THAT CONNECTS ANY NEEDLE (FEMALE LUER CONNECTOR) SOFT TUBING, AND THE TUBE HOLDER WITH THE PLASTIC NEEDLE.

OUR DEVICES HAVE THE SAME INTENDED USE AS THE IDENTIFIED PREDICATE DEVICES. IT IS USED FOR BLOOD COLLECTION AND AIDS IN THE PREVENTION OF NEEDLE STICK INJURIES. IT IS GOING TO BE USED BY PHLEBOTOMISTS AND NURSES IN HOSPITALS, DOCTORS OFFICES OR ANY OTHER PLACE WHERE BLOOD IS DRAWN.

NONE OF THE EXISTING DEVICES COMBINES BUTTERFLY WITH NEEDLE HOLDER. THOUGH IT IS HARD TO COMPARE IT AS A WHOLE TO ONLY ONE PREDICATE

BEING THAT SAFESTING IS AN EXTENTION OF DAISY PROTECTED SCALP VEIN SET; ALL MATERIALS USED ARE IDENTICAL, THE ONLY MODIFICATION BEING THE TUBE HOLDER/MULTISAMPLE ADAPTOR. THIS PART IS MADE OF POM.

SAFESTING HUB IS IDENTICAL TO SAFESTING WITHOUT THE BUTTERFLY PART, OFFERING THE POSIBILITY TO CONNECT TO ANY NEEDLE.

DURING THE SIMULATED CLINICAL TESTING, SAFESTING PERFORMED VERY WELL. 100% OF EVALUATORS WERE ABLE TO USE THE DEVICE WITH MINIMAL TRAINING. NEITHER HAND SIZE OR PREVIOUS EXPERIENCE HAD ANY BEARING ON PERFORMANCE. THE DEVICE PERFORMED IN 100% OF CASES IT WAS SAFE AND EFFECTIVE IN PREVENTING NEEDLE STICK INJURY. DUE TO REDUCED HANDELING (IT IS ONE COMPLETE PIECE) IT FURTHER REDUCED POSIBILITY OF INJURY.

All performance data is identical to Daisy in regards to blood drawing procedures and its safety feature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2001

Ms. Monica Abeles
President
Diasol Incorporated
13212 Raymer Street
North Hollywood, California 91605

Re: K011003
Trade/Device Name: Safesting and Safesting Hub
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: April 4, 2001
Received: April 4, 2001

Dear Ms. Abeles:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

c. Indications for use statement

Device Name: Safesting and Safesting Hub

Indications for use: Blood drawing device
Aids in the prevention of needle sticks injury.

Please do not write below this line

Concurrence of CDRH, Office of device evaluation (ODE)

Prescription Use ✓
Per 21 CFR 801.109

Rebecca Chevarek

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) K011003